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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,352	05/01/2001	Steven L. Stice	P 0280611	3443

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	3

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/845,352	Applicant(s) STICE ET AL.	
	Examiner Joseph Woitach	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6,15-25,33-35 and 47-55 drawn to methods of treating Parkinson's Disease with a cloned ungulate fetal dopamine cell or fetal dopamine neuronal cell line, a fetal dopamine neuronal cell line, classified in class 424, subclass 93.2.

II. Claims 1,7-9,11,18,26-28,33,36-38,40 and 55 drawn to methods of treating an a patient comprising administering a cell or tissue comprising a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is gp39, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is gp39, classified in class 424, subclass 93.21.

III. Claims 1,7,8,10,18,26,27,29,30,32,33,36,37,39 and 55, drawn to methods of treating an a patient comprising administering a cell or tissue comprising a heterologous nucleic acid encoding a suicide gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding a suicide gene, classified in class 424, subclass 93.21.

IV. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating Parkinson's Disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells

or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

V. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating Huntington's Disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

VI. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating Alzheimer's Disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

VII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating ALS comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue

comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

VIII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating spinal cord defect or injury comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

IX. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating epilepsy comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

X. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating multiple sclerosis comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XI. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating muscular dystrophy comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating cystic fibrosis comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned

genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XIII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating liver disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XIV. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating diabetes comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.XI.

XV. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating heart disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells

or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XVI. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating cartilage defects or disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XVII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating burns comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XVIII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating foot ulcers comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue

comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XIX. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating vascular disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XX. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating urinary tract disease comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XXI. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating AIDS comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XXII. Claims 1,7,8,11,12,18,33,36-38,40-43,46 and 55 drawn to methods of treating cancer comprising administering or transplanting a cell or tissue obtained from a cloned ungulate animal or embryo, wherein the cell or tissue comprises a heterologous nucleic acid encoding a growth factor, a cytokine, a protein or peptide that increases survival of the transplanted cells or decreases or inhibits adverse immune reactions or rejection of the transplant, and where the protein is an antiapoptosis gene, a cloned genetically modified cell line comprising a heterologous nucleic acid encoding an antiapoptosis protein, classified in class 424, subclass 93.21.

XXIII. Claims 1,7,8,13,14,18,33,36-38,44,45 and 55, drawn to methods of treating an a patient comprising administering a cell or tissue comprising a deletion of native DNA that decreases or eliminates the expression of an antigen that stimulates rejection, classified in class 424, subclass 93.21.

The inventions are distinct, each from the other because:

Inventions I and II-XXIII are mutually exclusive and independent inventions. The method of invention I is to a method of treating Parkinson's Disease by administering a cell or tissue from a cloned ungulate or embryo where the cell or the tissue does not contain a genetic modification. The methods of inventions II-XXIII are to methods of treating many diseases by administering a cell or tissue from a cloned ungulate or embryo where the cell of the tissue has been genetically modified. The transplanted cells or tissue are materially different and separate. Further the method of invention I is not needed for any of methods of inventions II-XXIII, and vice versa.

Inventions II-XXIII are mutually exclusive and independent methods of treatment. Each method is directed to treatment with cells comprising heterologous DNA sequences encoding materially different proteins or with cells comprising a deletion of a particular coding region of the genome designed to treat a particular disease or to treat by a particular mechanism of action. Each of inventions II-XXIII are not needed for the implementation any other invention of II-XXIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 703-308-1126. The examiner can normally be reached on M-Th and Tu-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Deborah Crouch

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

dcrouch
May 22, 2002